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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/322,289	SCHENK, DALE B.	
	Examiner	Art Unit	
	DANIEL KOLKER	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 – 2, 4, 6-8, 10-12,17, 21-28,31-37,56-58,60-90, 93-104* is/are pending in the application.

4a) Of the above claim(s) *25-28,33,34,56-58 and 60-81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6-8,10-12,17,21-24,31,32,35-37,82-90 and 93-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/11/08,6/24/08/7/30/08,8/7/08,8/20/08 (5 IDSs), 8/25/08,9/25/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The remarks and amendments filed 7 August 2008 have been entered. Claims 1 – 2, 4, 6-8, 10-12,17, 21-28,31-37,56-58,60-90, 93-104 are pending.

Election/Restrictions

2. Claims 25 – 28, 33 – 34, 56 – 58, and 60 – 81 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 19 December 2000.

3. Claims 1 – 2, 4, 6 – 8, 10 – 12, 17, 21 – 24, 31 – 32, 35 – 37, 82 – 90, and 93 – 104 are under examination.

Withdrawn Rejections and Objections

4. The following rejections and objections set forth in the previous office action are withdrawn:

A. The rejection under 35 USC 112, first paragraph, for lack of enablement commensurate in scope with the claims is withdrawn in light of the amendments. The claims no longer cover embodiments that would require undue experimentation to practice.

B. The rejections under 35 USC 103(a) over Becker in view of Walker, Hanan, and Majocha (paragraph 22 on p. 12 of the office action mailed 7 February 2008), as well as all rejections that depend from this initial rejection (that is, paragraphs numbered 23 – 27 spanning pp. 15 – 18 of the office action mailed 7 February 2008) are withdrawn in light of the arguments and the newly-presented reference by Hussain (reference 1092 on IDS filed 7 August 2008). Applicant persuasively argues that mouse IgG1 is not identical to human IgG1, which is recited in independent claims 1 and 82. The reference by Hussain, published four years before the filing of this application, supports this assertion, particularly at p. 729 second column. Thus combination of the teachings of Becker, Walker, Hanan, and Majocha would not result in arriving at the invention claimed, which requires administration of antibodies which are human IgG1 isotype.

C. The provisional obviousness-type double-patenting rejections over application 11/520438 and over 10/828548 in view of Becker are withdrawn in light of the arguments. As stated in the previous paragraph, the examiner concedes that references which render obvious

administration of humanized 10D5 antibody do not meet all limitations of the claimed invention, as mouse IgG1 antibodies do not correspond to human IgG1 antibodies.

Maintained Rejections and Objections

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 2, 4, 6 – 8, 10 – 12, 17, 21 – 24, 31 – 32, 35 – 37, 82 – 90, and 93 – 104 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 19 of U.S. Patent No. 6,743,427. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the instant case the claims allow for administration of antibodies generically whereas in the issued claims the antibodies must bind a specific epitope of Aβ.

This rejection stands for the reasons of record. Applicant did not traverse the rejection but indicated a terminal disclaimer may be filed in the future. However no such disclaimer has been filed so the rejection stands for the reasons of record.

6. Claims 1 – 2, 4, 6 – 8, 10 – 12, 17, 21 – 24, 31 – 32, 35 – 37, 82 – 90, and 93 – 104 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 36 of U.S. Patent No. 6,761,888. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the instant case the claims allow for administration of antibodies generically whereas in the issued claims the antibodies must bind a specific epitope of Aβ. Note that the issued claims encompass therapeutic and prophylactic treatment, (see claim 1), administration of human IgG1 antibodies (claim 19), as well as humanized (claim 14), chimeric (claim 15), and monoclonal antibodies (claim 17).

This rejection stands for the reasons of record. Applicant did not traverse the rejection but indicated a terminal disclaimer may be filed in the future. However no such disclaimer has been filed so the rejection stands for the reasons of record.

7. Claims 1 – 2, 4, 6 – 8, 10 – 12, 17, 21 – 24, 31 – 32, 35 – 37, 82 – 90, and 93 – 104 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 38 of U.S. Patent No. 6,913,745. Although the conflicting claims are not identical, they are not patentably distinct from each other because they differ only in scope; the issued claims of the '745 patent are limited to administration of specific humanized antibodies whereas the instant claims are generic with respect to which antibodies are to be administered. Note that the issued claims encompass humanized (claims 12, 31), monoclonal (claims 16 and 35), and chimeric antibodies (claims 14 and 33).

This rejection stands for the reasons of record. Applicant did not traverse the rejection but indicated a terminal disclaimer may be filed in the future. However no such disclaimer has been filed so the rejection stands for the reasons of record.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 - 2, 4, 10 - 12, 22-24, 31-32, 36, 82-84, 88-90, 95-99, 101, and 103-104 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Becker (EP 0 613 007, published 18 February 1994, cited on IDS filed 8 January 2001) in view of Kuby (1997. Immunology, Third Edition, p. 123, cited in office action mailed 17 November 2006), Adair et al. (WO 91/16928, cited in office action mailed 17 November 2006), and Janeway 1997 (Immunology, 3rd Edition pp. 8:18 - 8:19).

This rejection stands for the reasons previously made of record and explained in further detail below. Briefly, Becker teaches administration of antibodies raised against Aβ peptide for treatment of Alzheimer's disease. Becker specifically speaks to the advantages of using humanized antibodies; see columns 5 – 6. The reference also teaches diagnosis, i.e. administration to patients not yet known to have disease, as encompassed by claims 82-84, 88-90, 95-99, 101, and 104. The reasons why the limitations of the specific claims are met by the reference have been set forth in previous office actions. Note claims 4, 10 - 12, 22-24, 31-32, 36 recite the same limitations as claims 84, 88-90, 95-99, and 101 respectively; they differ only in that the latter set of claims depend from claims 82-83 rather than 1-2. However Becker does not explicitly teach administration of antibodies of isotype IgG1 as recited in claims 1 and 82.

Kuby teaches the structure of human IgG isotypes and teaches that they vary in size and in the structure of the hinge region. Kuby further teaches that the subtle differences in amino acid sequences between the various IgG classes lead to differences in the hinge region, and that these subtle difference also lead to differences in biological activities of the various classes of IgG isotypes (p. 123 second column first complete paragraph). Finally Kuby teaches that the classes (or isotypes) are determined not by the antigen binding region but by the constant region, which remains constant for any given isotype independent of the antigen bound. However Kuby does not teach specific advantages of isotype IgG1.

Adair teaches that the binding affinity of humanized antibodies which bind to ICAM-1 varies with isotype. Adair teaches that IgG1 isotype binds more strongly than other isotypes, and this is due to the structure of the hinge and constant regions of IgG1, providing motivation to the artisan of ordinary skill to select IgG1 antibodies based on their strong ability to bind to

antigens. See especially pp. 22 – 23. However Adair does not teach administration of antibodies that bind to Aβ protein as recited in claim 1 or 82.

Janeway teaches that there are four isotypes of human IgG, and presents a chart which shows the properties and advantages of each of these isotypes; see Figure 8.16. Janeway teaches that IgG1 is particularly suited to neutralizing and is able to diffuse into extravascular sites. However Janeway does not teach administration of antibodies that bind to Aβ protein as recited in claim 1 or 82.

It would have been obvious to one of ordinary skill in the art to select antibodies of isotype IgG1, as suggested by Kuby, Adair, and Janeway for use in the methods of Becker, with a reasonable expectation of success. The motivation to do so would be to select antibodies that bind tightly to the target antigen; this motivation flows directly from the prior art references themselves. Becker teaches that the treatment with antibodies is efficacious; Adair teaches that antibodies of IgG1 isotype bind to antigens very well, and Kuby teaches that the biological properties of the specific isotypes is dependent upon the structure of the constant region, not the variable (antigen-binding) domain. Additionally, Janeway provides more detailed listings of the properties of each of the different human IgG isotypes, and indicates that IgG1 is particularly suited to diffusion into extravascular sites. The artisan of ordinary skill would have found it both obvious and advantageous to select the IgG1 isotype for administration, particularly for administration by intraperitoneal, intramuscular, oral, topical, or intravenous routes as recited in claim 32 for example. Because of its ability, described by Janeway, to exit the vascular system, which would allow it to have its effects within neural tissues, the artisan of ordinary skill would be motivated to select IgG1. Note that Becker teaches that routes of administration including intravenous are suitable for the methods disclosed therein (see column 8 lines 38 - 42), so the artisan of ordinary skill would be motivated to select antibodies that exit the vascular system.

Applicant argues, at pp. 11 – 17 of the remarks, that the claimed invention would not have been obvious to one of ordinary skill in the art at the time the invention was made. Applicant makes the following points, each of which will be addressed in turn:

1) The examiner has improperly generalized the findings of Adair, which mentions a single example of an IgG1 antibody having higher affinity for an antigen than other isotypes, to all antibodies.

2) The present facts and circumstances are sufficiently different from those in the decision of *KSR v. Teleflex* that the logic in that case should not apply here.

3) Numerous disinterested parties characterized a paper describing results of methods similar to those now claimed as “surprising”, “amazing”, or “revolutionary”, and that such comments are indicative of non-obviousness of the claimed invention.

4) The prior art references, particularly that by Becker, should not be considered enabling as the technology was unpredictable when that reference was published, and the reference supplies no data in support of the statements as to treatment or diagnosis of Alzheimer’s by administration of antibodies against Aβ.

Applicant’s arguments have been fully considered but they are not persuasive. With respect to 1) above, the reference by Adair provides the artisan of ordinary skill with specific reasons to select IgG1 for administration in the methods of Becker. Specifically, the reference indicates that antibodies of isotype IgG1 bind more strongly to their cognate antigen than do antibodies of other isotypes. Adair teaches that this increased binding affinity is due to the specific structure of the hinge region. The reference by Kuby indicates that the various isotypes differ from one another in regions outside of the antigen-binding regions, including the structure of the hinge region. Thus Kuby provides the artisan of ordinary skill with a sound scientific reason to expect that IgG1 would bind more tightly to its target antigen than would other isotypes, as the constant and hinge regions which are common to all human IgG1 antibodies provide the relevant property. The examiner believes that this logic, on its own, provides sufficient motivation to the artisan of ordinary skill to select antibodies of the IgG1 isotype for administration in the claimed methods. Nonetheless, in order to provide even further motivations to select this antibody, the examiner has cited the prior art reference by Janeway, which lists the several advantages in selecting IgG1. Because this reference is newly-cited, the present office action is non-final.

With respect to 2) and 3) above, on pp. 12 – 14 applicant argues that “the present facts and circumstances are, however, entirely different from *KSR*.” (remarks, p. 13) Applicant argues that in *KSR* the claims were directed to combination of electronic sensors and foot pedals, whereas here the claims are drawn to treatment or prophylaxis of Alzheimer’s disease. According to applicant, the latter is so highly unpredictable that one of ordinary skill in the art could not select from a limited number of possible therapies and have an expectation of success in treatment of disease as claimed. Additionally, applicant argues that the statements of surprise by neutral experts in the field as to the success of Dr. Schenk’s approach are themselves indicative of non-obviousness.

These arguments have been fully considered but they are not persuasive. While the present facts are not identical to those in *KSR* (the latter being drawn to parts of a car, while this case is drawn to treatment or delaying outset of Alzheimer's disease), the issues are analogous. In *KSR*, the issue was whether the differences between the claimed invention and those in the prior art were so great as to overcome the examiner's determination of obviousness. The court ruled that the differences between the prior art references, which taught all elements of the claimed invention, albeit not in a single reference, were not so great as to constitute a non-obvious difference from those references. In the present case, the prior art references teach all elements of the claimed invention. Becker teaches administering chimeric humanized antibodies raised against Aβ to patients for treatment or diagnosis of Alzheimer's disease (diagnosis being considered a specific form of administration to asymptomatic patients as encompassed by claim 82); the only element that Becker fails to teach is the specific IgG1 isotype. This deficiency is remedied by Kuby, Adair, and Janeway who together teach the properties of IgG1 and provide reasons to select this specific isotype. Note that in particular Janeway indicates the predictable nature of the different isotypes; the reference indicates that the various properties listed are general to all antibodies of a given isotype, and are not dependent upon the antigen bound.

With respect to the statements of surprise by neutral experts, listed on pp. 13 – 14 of the remarks filed, the comments are directed to the reportedly surprising success at the approach of immunizing mice, rather than selecting IgG1 in particular. The experts state that Dr. Schenk's "goal was to raise an antibody or other immune response against plaques" and that "Schenk surprised the Alzheimer's research community in June 1999 when he announced the vaccine worked". While the specific experiment reported by Dr. Schenk's research group in 1999 was directed to administration of Aβ peptide rather than antibody, the hypothesized therapeutic mechanism is the same in either case: that antibodies, either made by the host or administered exogenously, will have a therapeutic effect. This is the aspect that the experts found surprising and unexpected. However, this same approach is exactly what Becker teaches. At column 7 lines 39 – 52, Becker specifically teaches that artisan of ordinary skill that Alzheimer's disease is to be treated by administering antibodies that bind to Aβ. Thus contrary to applicant's statements, the approach of administering antibodies against Aβ (or Aβ peptide in an amount sufficient to elicit an antibody response, as was done in the experiments the experts commented upon) was not a departure from the prior art, but merely following the directions published by

Becker and his research group at Athena Neurosciences in 1994. The claimed invention differs from the Becker reference only by specifying human IgG1 antibodies. For the reasons set forth above, selection of this particular isotype would have been obvious, particularly given the limited number of possible isotypes and their well-known properties (see Janeway, for example).

With respect to 4) above, applicant argues that since the technology of treating Alzheimer's disease was unpredictable at the time the invention was made, the reference by Becker should not be considered enabling as no specific results or clinical data, or even *in vitro* data, were presented to support the statements that the antibodies are therapeutic or diagnostic for Alzheimer's. Applicant argues that the guidance in MPEP § 2121 should not apply in the present case. The examiner respectfully disagrees. The MPEP cites specific cases which form the basis of the office's guidance to examiners on this issue. MPEP § 2121(I) states that:

> When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980).

Here, applicant has provided no evidence that the prior art reference in question (Becker) is non-operable. Absent such evidence, the Becker reference is presumed to be operable. Additionally, the reference need not disclose actual success in terms of clinical trials in order to be enabling. MPEP § 2121(III) states that

> A prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention; "proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation." *Impax Labs. Inc. v. Aventis Pharm.Inc.,* 468 F.3d 1366, 1383, 81 USPQ2d 1001, 1013 (Fed. Cir. 2006).

While that discussion is on point to anticipation, the same logic applies to determinations of obviousness. With the exception of the specific isotype human IgG1, Becker teaches every element of the claimed invention as described in detail in previous office actions. Becker teaches the artisan of ordinary skill that Alzheimer's can be treated by administering antibodies against Aβ, including chimeric humanized antibodies. While the field of Alzheimer's disease treatment was certainly difficult in the 1990s, and in fact remains difficult today, the lack of

explicit data supporting the teachings of Becker does not mean that the reference is not enabling.

Applicant also argues that it appears the examiner is improperly relying on hindsight reconstruction in maintaining this rejection. Of course all determinations of obviousness are necessarily made in hindsight (MPEP § 2145(X)(A)); the examiner has carefully weighed all the evidence that was available at the time of filing and has determined that selection of the specific isotype recited in the claims would have been an obvious choice to one of ordinary skill in the art, possessed with the knowledge taught by Becker. The examiner has attempted to avoid improper hindsight reasoning, and has attempted to make determinations as to whether or not it would have been obvious to one of ordinary skill in the art to modify the teachings of Becker, given the teachings of Kuby, Adair, and Janeway. The examiner has concluded that claims 1 - 2, 4, 10 - 12, 22-24, 31-32, 36, 82-84, 88-90, 95-99, and 101 are unpatentable as obvious for the reasons previously made of record and discussed above.

Claims 103 – 104 are included in this rejection for the reasons set forth on p. 6 final paragraph of the office action mailed 7 August 2008. The claims recite certain properties of the antibodies that appear to be inherent. The claims do not recite any further structural limitations beyond those of the base claims from which they depend. The examiner is unable to determine if the prior art antibodies rendered obvious by Becker in view of Kuby, Adair, and Janeway have these properties or not. However, it is proper to include these claims in this rejection; see MPEP § 2112(III). Additionally it is noted that Becker teaches antibodies which specifically bind Ab in general, and also teaches additional embodiments wherein the antibodies bind to the various forms of Aβ in more specific fashion. The antibodies which bind to Aβ generically would be presumed to bind to all forms. The burden is on applicant to provide evidence of non-obviousness; see MPEP § 2112(V). As claims 103-104 recite no further structural features, they are properly included in this rejection.

9. Claims 1 - 2, 4, 10 - 12, 22-24, 31-32, 35-36, 82-84, 88-90, 95-99, 100-101, and 103-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becker in view of Kuby, Adair, and Janeway as applied to claims 1 - 2, 4, 10 - 12, 22-24, 31-32, 36, 82-84, 88-90, 95-99, 101, and 103-104 above, and further in view of Miller (U.S. Patent 5,227,159 (of record)).

This rejection stands for the reasons of record. Applicant did not separately traverse the examiner's determination that the limitations recited in claims 35 and 100 would have been obvious to one of ordinary skill in the art given the teachings of Miller.

10. Claims 1 - 2, 4, 10 - 12, 22-24, 31-32, 36-37, 82-84, 88-90, 95-99, and 101 -104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becker in view of Kuby, Adair, and Janeway as applied to claims 1 - 2, 4, 10 - 12, 22-24, 31-32, 36, 82-84, 88-90, 95-99, 101, and 103-104 above, and further in view of Sabel (U.S. Patent 4,883,666, of record).

This rejection stands for the reasons of record. Applicant did not separately traverse the examiner's determination that the limitations recited in claims 37 and 102 would have been obvious to one of ordinary skill in the art given the teachings of Sabel.

11. Claims 1 - 2, 4, 6-8, 10 - 12, 22-24, 31-32, 36, 82-90, 95-99, 101, and 103-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becker in view of Kuby, Adair, and Janeway as applied to claims 1 - 2, 4, 10 - 12, 22-24, 31-32, 36, 82-84, 88-90, 95-99, 101, and 103-104 above, and further in view of Brookmeyer (1998. American Journal of Public Health 88:1337-1342, of record.

This rejection stands for the reasons of record. Applicant did not separately traverse the examiner's determination that the limitations recited in claims 6-8 and 85-87 would have been obvious to one of ordinary skill in the art given the teachings of Brookmeyer.

12. Claims 1 - 2, 4, 10 - 12, 17, 22-24, 31-32, 36, 82-84, 88-90, 93, 95-99, 101, and 103-104 rejected under 35 U.S.C. 103(a) as being unpatentable over Becker in view of Kuby, Adair, and Janeway as applied to claims 1 - 2, 4, 10 - 12, 22-24, 31-32, 36, 82-84, 88-90, 95-99, 101, and 103-104 above, and further in view of Yachi (EP 0 285 159, of record).

This rejection stands for the reasons of record. Applicant did not separately traverse the examiner's determination that the limitations recited in claims 17 and 93 would have been obvious to one of ordinary skill in the art given the teachings of Yachi.

13. Claims 1 - 2, 4, 10 - 12, 21-24, 31-32, 36, 82-84, 88-90, 94-99, 101, and 103-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becker in view of Kuby, Adair, and Janeway as applied to claims 1 - 2, 4, 10 - 12, 22-24, 31-32, 36, 82-84, 88-90, 95-99, 101, and

103-104 above, and further in view of Zhang et al. (1998. Current Protocols in Molecular Biology 10.15.1 - 10.15.9).

This rejection stands for the reasons of record. Applicant did not separately traverse the examiner's determination that the limitations recited in claims 21 and 94 would have been obvious to one of ordinary skill in the art given the teachings of Zhang. Note the same limitation appears in claim 94.

14. Claims 82 – 84, 87 – 90, 95 – 99, 101 – 102, and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (US 5,589,154, of record) in view of Kuby (1997. Immunology, Third Edition, p. 123, cited in office action mailed 17 November 2006) Adair et al. (WO 91/16928, cited in office action mailed 17 November 2006), and Janeway 1997 (Immunology, 3rd Edition pp. 8:18 - 8:19).

This rejection stands for the reasons of record. Applicant did not separately traverse the examiner's determination that the references by Anderson, Kuby, and Adair render obvious the recited claims. The examiner has included the reference by Janeway, which points out the particular features of IgG1, in this rejection as well. If the references by Kuby and Adair were in any way deficient in their guidance to select IgG1, this alleged deficiency is cured by Janeway, discussed above.

15. Claims 82 – 84, 87 – 90, 95 – 99, 100 – 102, and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kuby, Adair, and Janeway as applied to claims 82 – 84, 87 – 90, 95 – 99, 101 – 102, and 104 above, and further in view of Miller (U.S. Patent 5,227,159, of record).

This rejection stands for the reasons previously made of record. Applicant did not separately traverse the examiner's determination that the limitations recited in claim 100 would have been obvious to one of ordinary skill in the art given the teachings of Miller.

16. Claims 82 – 84, 85 – 90, 95 – 99, 101 – 102, and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kuby, Adair, and Janeway as applied to claims 82 – 84, 87 – 90, 95 – 99, 101 – 102, and 104 above, and further in view of Brookmeyer (1998. American Journal of Public Health 88:1337-1342).

This rejection stands for the reasons previously made of record. Applicant did not separately traverse the examiner's determination that the limitations recited in claims 85-86 would have been obvious to one of ordinary skill in the art given the teachings of Brookmeyer.

17. Claims 82 – 84, 87 – 90, 93, 95 – 99, 101 – 102, and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kuby, Adair, and Janeway as applied to claims 82 – 84, 87 – 90, 95 – 99, 101 – 102, and 104 above, and further in view of Yachi (EP 0 285 159, published 10 May 1988).

This rejection stands for the reasons previously made of record. Applicant did not separately traverse the examiner's determination that the limitations recited in claim 93 would have been obvious to one of ordinary skill in the art given the teachings of Yachi.

18. Claims 82 – 84, 87 – 90, 95 – 99, 101 – 102, and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kuby, Adair, and Janeway as applied to claims 82 – 84, 87 – 90, 95 – 99, 101 – 102, and 104 above, and further in view of Zhang et al. (1998. Current Protocols in Molecular Biology 10.15.1 - 10.15.9).

This rejection stands for the reasons previously made of record. Applicant did not separately traverse the examiner's determination that the limitations recited in claim 94 would have been obvious to one of ordinary skill in the art given the teachings of Zhang.

New Rejections

Double Patenting

19. Claims 82 - 83, 85 - 86, 89 - 90, 97 - 100, and 104 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3 – 17 of U.S. Patent No. 6,710,226. Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass administration of humanized antibodies that bind to Aβ to patients susceptible to Alzheimer's, wherein the antibody is human isotype IgG1; see in particular claim 13 of the '226 patent. While certain claims in the'266 patent require additional steps not recited in the pending claims, the pending claims subject to this rejection are generic and allow for inclusion of other elements as they use open "comprising" claim language. The issued claims would anticipate the claims listed in the first sentence of this paragraph.

Conclusion

20. No claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker, Ph.D./
Primary Examiner, Art Unit 1649
October 31, 2008